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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Kenji Sunagawa

KUP-6

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

NOTIFICATION DATE

DELIVERY MODE

04/07/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/523,538	<b>Applicant(s)</b> SUNAGAWA, KENJI	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/24/2010 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner was unable to find support for the closed-ended exclusionary transition phrase "consisting of" in the originally-filed disclosure. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to

Art Unit: 3762

comply with the written description requirement. See MPEP 2173.05(i). Although page 8 indicates that the fuel cell "is composed of an anode (41) and a cathode (42)," the transition phrase "composed of" has been interpreted to mean either "consisting essentially of" or "consisting of," based on the facts of the case. See MPEP § 2111.03. Based on the facts of this case (see the "scope of enablement" rejection below), the examiner is of the position that "composed of" must mean "consisting essentially of" because merely providing an anode and cathode (without providing connecting wires or a housing structure or other element to maintain separation between the anode and cathode) could not result in a functioning fuel cell. A fuel cell requires more than *just* an anode and cathode because separation between the two elements must be maintained (e.g., provided by the housing in Applicant's figure 2).

4. Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a fuel cell "comprising" or "consisting essentially of" an anode and a cathode, does not reasonably provide enablement for a fuel cell "consisting of" an anode and cathode. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Because separation between an anode and cathode must be maintained for a fuel cell to operate (e.g., provided by the housing in Applicant's figure 2) and the fuel cell requires other elements, such as the semi-permeable membrane(s) and wiring to a load, a functioning fuel cell cannot *consist of* only a cathode and anode.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (US 3,943,936, hereinafter "Rasor") in view of Heller (US 6,294,281, hereinafter "Heller"). Rasor discloses the essential features of the claimed invention, including a pacemaker capable of implantation with the tip of a catheter and requiring no chest incision (Figs. 5A-5C and 9) having a control unit (30), a heart stimulating means (output of 30), an electrocardiograph information detecting means ("trigger input" and col. 11, lines 8-13), and a fuel cell power unit (col. 3, lines 19-21), wherein the control unit outputs the control signal based on the ECG information (col. 11, lines 8-13). Further, Rasor discloses that the control unit comprises a stimulation timing determining means ("pulse forming circuit") that decides the timing of pulses and a stimulation timing changing means (col. 11, lines 15-18) that changes the timing of stimulation when certain conditions are met. Rasor does not disclose that the fuel cell is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels consisting of an anode and cathode; wherein the anode is coated with immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen

Art Unit: 3762

and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid without the need for a container to contain the electrolyte solution or metabolic product; and wherein the anode and cathode contact the electrolyte solution. Heller teaches a biological fuel cell for use with implantable devices (col. 2, lines 60-67) that extracts electrons from oxidative reactions of biological fuels consisting of an anode and a cathode (col. 3, line 22 -- the spacer elements are optional); wherein the anode is coated with an immobile layer of mediators (redox polymer layer; cols. 5-9) and oxidative enzymes for biological fuels (cols. 9-12), wherein the layer prevents oxygen existing in a biological body from contacting the anode (col. 8, line 16; "poly(acrylic acid)"), and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions (col. 13, lines 21-47 and col. 14, lines 4-18); wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid without the need for a container to contain the electrolyte solution or metabolic product (col. 14, lines 35-43 and Fig. 1); and wherein the anode and cathode contact the electrolyte solution (col. 14, lines 35-43) to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rasor's invention by providing a biological fuel cell for use with implantable devices that extracts electrons from oxidative reactions of biological fuels consisting of an anode and cathode; wherein the anode is coated with

Art Unit: 3762

immobile layer of mediators and oxidative enzymes for biological fuels, wherein the layer prevents oxygen existing in a biological body from contacting the anode, and a cathode electrode coated with a material capable of preventing permeation of reactive substances other than oxygen and allowing permeation of oxygen and hydrogen ions; wherein the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid; and wherein the anode and cathode contact the electrolyte solution to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Please note that Heller's coating material (poly(acrylic) acid) inherently prevents oxygen existing in a biological body from contacting the anode. See Reichert et al. (US 5,270,128; col. 3, lines 40-65) as evidence of inherency. In the alternative, it is notorious in the fuel cell arts to prevent oxygen from contacting anodes to provide the predictable result of avoiding degradation of the anode material. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by preventing oxygen from contacting the anode to provide the predictable result of avoiding degradation of the anode material.

**7.** Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor in view of Heller and Fujii et al. (US 5,411,535, hereinafter "Fujii"). Rasor's modified invention (as applied to claim 10) discloses the essential features of the claimed invention except for a transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit. Fujii teaches an implantable pacemaker, similar to the one taught by Rasor, with

Art Unit: 3762

transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit (Fig. 7) to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by providing transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body.

### ***Response to Arguments***

8. Applicant's arguments filed 3/24/2010 have been fully considered but they are not persuasive. Applicant argued that Rasor discloses only removal of a worn pacemaker by catheter, while Applicant's pacemaker is inserted and removed by catheter. However, Figures 5a, 5b, and 5c clearly depict insertion of the device via catheter. Applicant further argued that the preamble limitation "integrated" requires the capability to link with at least one other pacemaker unit. However, the examiner respectfully maintains that a fair reading of "integrated" does not require such limitations. For instance, a plain meaning of "integrated" is "formed into a whole." This meaning does not necessarily require other pacemakers or the capability to link with other pacemakers, but only a pacemaker "formed into a whole." As Rasor's pacemaker is structurally integrated, the examiner respectfully maintains the rejection. Applicant



Art Unit: 3762

further argued that Rasor discredits/"teaches away" from a fuel cell because Rasor uses a mechanical transducer and discredits energy derived from heart movement.

However, it is not clear how Rasor's alleged teaching away from a mechanical power source is a teaching away from a chemical fuel cell. Rasor explicitly indicates at column 3, line 21 that the power source is a fuel cell. Rasor does not teach away from a modification including providing a fuel cell because no modification is proposed -- Rasor explicitly discloses providing a fuel cell. Rasor is merely lacking explicit disclosure of the specific features of the "well-known conventional fuel cell" that Applicant discloses on page 8 of the disclosure and Heller further teaches. Applicant further argued that Heller provides spacers between the anode and cathode, and thus the fuel cell does not "consist of" an anode and cathode. However, Heller discloses that these spacers are optional (col. 3, line 22). Additionally, the claimed "anode" and "cathode" cannot fairly be interpreted as merely the anode electrode and cathode electrode material (as indicated by the claim language and shown in, *e.g.*, Figure 2 of Applicant's disclosure), but also include other elements, such as the coatings on the respective electrodes. Under this reading, either the anode or the cathode of Heller can be considered to include additional elements such as a spacer, and thus the fuel cell "consists of" an anode and cathode, but the anode (or cathode) element comprises a spacer.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHRELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

Art Unit: 3762

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/  
Examiner, Art Unit 3762